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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,738	10/12/2004	Mitsuaki Kawamura	04676.0142	8582
22852	7590	11/20/2009		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER KAROL, JODY LYNN	
			ART UNIT	PAPER NUMBER
			1627	
			MAIL DATE	DELIVERY MODE
			11/20/2009 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/510,738

**Applicant(s)**

KAWAMURA ET AL.

**Examiner**

Jody L. Karol

**Art Unit**

1627

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/30/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6-9, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-9, and 39-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/30/2009. Claims 1 and 39 have been amended. Claims 4-5 have been cancelled. Claims 2-3 and 10-38 were previously cancelled. Claim 40 is newly added. Thus, claims 1, 6-9, and 39-40 are pending and currently under consideration.

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 7/30/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 10/574,696 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### **WITHDRAWN REJECTIONS**

1. Applicant's cancellation of claims 4-5 and the submission of the terminal disclaimer filed on 7/30/2009 renders the rejection of claims 1 and 4-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-15 of copending Application No. 10/574,696 in view of Collins et al. (US 6,203,805 B1) moot. Thus, said rejection is herein withdrawn.
2. Upon further consideration, the rejection of claim 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is herein withdrawn.

3. In view of Applicant's amendment to claim 39, the rejection of claim 39 under 35 U.S.C. 112, second paragraph, as being indefinite, is herein withdrawn.

4. In view of Applicant's amendments to claim 1, and cancellation of claims 4-5, the rejection of claims 1 and 4-9 under 35 U.S.C. 102(b) as being anticipated by Gil et al. (US 5,066,500) as evidenced by Zimmerman et al. (US 2002/0141955 A1) is herein withdrawn.

#### ***Response to Arguments***

5. Applicant's arguments filed 7/30/2009 have been fully considered but they are not persuasive.

Applicant alleges that nothing in Gil et al. or Zimmerman et al. instructs or suggests to one of ordinary skill in the art that the adenosine or its salt and the uridine and its salt should be split into two separate compositions, and the manufacturing of two separation compositions is more expensive and burdensome. In response it is respectfully submitted that infant formulas, such as those taught by Gil et al., are often administered to an infant several times of day. Thus, the division of the powdered infant formula into two separate compositions each containing the same components is obvious for the purpose of administering to the infant multiple times. It is noted that the contents of the first and second composition are dictated by "contains" which is interpreted as broad and open-ended. Thus, the claims essentially read on two

compositions containing identical components wherein the components include AMP, UMP and an additive, such as the compositions taught by Gil et al.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

#### **REJECTIONS**

6. The following rejections and/or objections are either reiterated from the previous Office Action dated 3/31/2009 or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. The newly applied rejections are necessitated by the amendment of claims 1 and 39, and the addition of new claim 40.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim is 40 rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al. (US 5,066,500) as evidenced by Zimmerman et al. (US 2002/0141955 A1).

Gil et al. teach non-milk based infant formulas and nutritionally balanced diet formulations comprising nucleosides and/or nucleotides (see abstract). The compositions preferably comprise the nucleotides cytidine monophosphate (CMP),

guanosine monophosphate (GMP), inosine monophosphate (IMP), adenosine monophosphate (AMP) and uridine monophosphate (UMP) (see column 5, lines 3-13). Gil et al. further teach examples of diet formulations comprising 150 mg/100g of AMP (0.150% by weight), 150 mg/100g UMP (0.150% by weight), and ascorbyl palmitate (see Examples VII-X, column 22, line 18 to column 27, end of Table XIII). The ratio of adenosine monophosphate to uridine monophosphate is 1:1, meeting the limitation of the instant claim 40. As evidenced by Zimmerman et al., ascorbyl palmitate is a whitening agent or whitener as claimed in the instant claim 1 (see pages 1-2, sections [011] and [0016]-[0017]).

It is noted that the intended use of the composition, i.e. for applying to the skin, is not accorded any patentable weight. "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 6-9, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gil et al. (US 5,066,500) in view of Zimmerman et al. (US 2002/0141955 A1) as applied to claim 40 above.

The instant claims are directed to compositions for applying to the skin containing adenosine monophosphate in 1 to 10% by weight, uridine monophosphate in 0.0001 to 10% by weight, and at least one additive

Gil et al. and Zimmerman et al. are described *supra* as applied to claim 40. Gil et al. further teach the range of nucleosides and/or nucleotides in the powdered product in nutritionally based diets ranges from 1 to 300 mg/100 mg for adenosine monophosphate and 1 to 300 mg/100 mg uridine phosphate (i.e. 1 to 3% by weight) (see column 10, Table III).

Gil et al. and Zimmerman et al. do not exemplify a composition comprising between 1 to 10% by weight of AMP as claimed in the instant claim 1. Gil et al. and Zimmerman et al. do not teach two separate compositions each containing an additive as claimed in the instant claim 39.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the amount of AMP present in the composition taught by Gil et al. One of ordinary skill in the art would have been motivated to optimize the amount of AMP to provide the desired nutritional profile. One of ordinary skill in the art would have had a reasonable expectation of success in optimizing the amount of AMP because Gil et al. teach the range of AMP in nutritionally balanced diets overlaps with the range of AMP as claimed.

In regards to claim 39, the arrangement of the components in the composition into two separate compositions is deemed obvious absence a showing of unexpected results. Further, if the additive for the two compositions is the same (i.e. a whitener), then there is no substantial difference between the components in the single composition and the components in the treatment.



Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/Yong S. Chong/  
Primary Examiner, Art Unit 1627